K103531

Tokyo Boeki Medisys Inc.
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DEC - 1 2011

5. 510(k) SUMMARY

Submitter's Name/Address

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Date of Preparation of this Summary: October 25, 2011

Device Trade or Proprietary Name: Biolis 24i, MGC 240 and Prestige 24i,
(These are the same models except the names)

Device Common Name: Clinical Chemistry Analyzer
(with optional ISE Module)

Classification Numbers/Class: 75JJE, Class I
75CFR Class II

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510(k) Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is : k103531

Description:

Using photometry, the Biolis 24i instrument measures the glucose concentration in serum by monitoring the change in absorbance at 340 nm. Additionally, the Biolis 24i with Ion-Selective Elective module additionally measures the concentration of the electrolytes, sodium, potassium and chloride in serum, using indirect potentiometry.

Intended Use:

The Biolis 24i Clinical Chemistry Analyzer is a discrete photometric clinical chemistry analyzer. The device is intended to duplicate manual analytical procedures by automating various steps such as pipetting, heating, measuring color intensity, and reporting results. The device is intended to be used with certain materials to measure various analytes of diagnostic interest including glucose. An optional Ion Selective Electrode Module is intended to measure sodium, potassium and chloride.

The Biolis 24i analyzer with glucose hexokinase assay is intended to measure glucose quantitatively in human serum. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic glycemia, and of the pancreatic islet cell carcinoma.

Substantial Equivalence:

Substantial equivalence has been demonstrated between the Beckman CX-7 (K904219) and the Biolis 24i. These analyzers are calibrated with known concentration calibrator material and both measure specific concentrations using photometry.

Comparison with predicate:

Item	New Device **Biolis 24i**	Predicate **SYNCHRON CX 7** (K904219)
General		
System Principle	Discrete, single line random access, multi-test analysis	Discrete, random access, multi-test analysis
Throughput	240 tests	225 tests/hr (photometric only)
Configuration	Analytical unit, Control unit	Analytical unit, Control unit
Measurement modes	Absorbance	Absorbance

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Detector	Photo-diode	Diffraction grating, photodiode array
Optical system	Wavelength range of 340 to 800nm	340, 380, 410, 470, 520, 560, 600, 650, 670, 700 nm
Light source	Tungsten halogen lamp	xenon
Reaction cuvettes	Plastics, semi disposal	quartz
Path length	8mm	5 mm
Reaction time	Maximum 10min.	Maximum 12 min.
Incubation temperature	37°C +/- 0.1°C	same
Glucose		Glucose hexokinase 510(k): k802810
Intended use	Quantitative determination of glucose in serum	Quantitative determination of glucose in serum plasma, urine, CSF
Method	Photometric endpoint using glucose hexokinase.	Same
Sample type	Serum	Serum, plasma, urine, CSF
Sample Volume	3 uL	same
Reaction Time	5 min ` Analysis time Read period: 52 - 54 points (15 seconds per point)	5 min

The validated system is described below.

Analyzer:	Tokyo Boeki BioLis 24i Analyzer, software revision: 1.26 Serial numbers are listed on individual data sheets.
Reagent:	Carolina Liquid Chemistries Glucose Reagent, Kit product no. BL-208 (also packaged as AU-208). Lot numbers are listed on individual data sheets.
Application parameters:	Sample volume: 3 µL Reagent volume: 310 µL Wavelengths: 340 / 405 nm Reaction type: Endpoint Read period: 52 - 54
Calibrator:	Pointe Scientific Chemistry Calibrator product no. C7506-50, lot 11802, exp. March 2014 Premarket clearance reference no.: K070207
	The 185 mg/dL glucose set point for the Pointe Calibrator was verified for the Carolina Liquid Chemistries Glucose Reagent by comparing the calibrator to NIST SRM 965b, Glucose in Frozen Serum. The Pointe Calibrator was assayed eight times over each of four analytical runs against NIST standard levels 3 and 4 which were each assayed in duplicate. The glucose concentration of the Pointe Calibrator was calculated for each run by linear interpolation the NIST assay values and their respective certified values of 118.5 mg/dL and 294.5 mg/dL. The mean glucose result of the Pointe Calibrator over the four runs was 185.6 mg/dL.

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Performance Characteristics <Glucose Hexokinase >

Method Comparison

A correlation analysis between the Beckman CX-7 and the Biolis 24i yielded the following results:

Representative Method	Correlation Coefficient	Slope (Least-Squares)	Y-axis intercept
GLU	0.999	0.974	2.22

Precision

Repeatability

Sample	N	Mean	SD	CV(%)
Serum 1	59	60.3	0.8	1.3%
Serum 2	60	106.4	1.4	1.3%
Serum 3	60	116.8	1.4	1.2%
Serum 4	60	192.1	2.2	1.1%
Serum 5	60	446.2	6.8	1.5%

Total Imprecision Study

Analyzer s/n	Sample	n	mean	SD	%CV
2229450610	Control 1	80	63.2	1.5	2.4%
	Serum Pool 1	80	118.1	2.9	2.5%
	Serum Pool 2	80	188.8	4.1	2.1%
	Control 2	80	447.0	10.5	2.3%
2227671109	Control 1	80	63.2	1.2	1.9%
	Serum Pool 1	80	117.6	2.7	2.3%
	Serum Pool 2	80	186.9	3.6	1.9%
	Control 2	80	445.9	9.8	2.2%

Linearity

The linearity test yielded the following results:

Correlation	0.9982
Slope	0.948
Intercept	2.45
Range	25 - 500 mg/dL

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Sensitivity

	mg/dL
LoB	3.64
LoD	5.64
LoQ	10

Interferences

Interferent	Interferent Concentration	Glucose Concentration	Observed Interference
Ascorbic acid	30 mg/L	75 mg/dL 140 mg/dL	none
Bilirubin	4.8 mg/dL 6.4 mg/dL	90 mg/dL 146 mg/dL	-3.3 mg/dL -3.6%
Hemoglobin	240 mg/dL 160 mg/dL	76 mg/dL 139 mg/dL	-3.6 mg/dL -3.8%*
Lipemia (from Intralipid)	600 mg/dL 80 mg/dL	72 mg/dL 142 mg/dL	+ 4 mg/dL + 3.9%
Metronidazole	24 mg/L 48 mg/L	76 mg/dL 139 mg/dL	+ 2.4 mg/dL + 3.1%
Tetracycline	15 mg/L	76 mg/dL 141 mg/dL	none

Conclusion

The data demonstrates that Biolis 24i is substantially equivalent to Beckman SYNCHRON CX 7 (K904219) and that the CLC Glucose Reagent is substantially equivalent to Beckman Glucose Reagent (K802810).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Tokyo Boeki Medisys Inc.
c/o James M Clinton
US Agent
5105 Fairoaks Road,
Durham, NC 27712

DEC - 1 2011

Re: k103531
Trade/Device Name: Biolis 24i Clinical Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name:Glucose test system
Regulatory Class: II
Product Code: CFR, JJE
Dated: November 4, 2011
Received: November 8, 2011

Dear Mr. Clinton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): k103531

Device Name: Biolis 24i Clinical Chemistry Analyzer

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 103531